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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,150	04/27/2005	Takayuki Taguchi	10921.315USWO	2382

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EXAMINER	
LEVKOVICH, NATALIA A	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,150	TAGUCHI ET AL.	
	Examiner	Art Unit	
	NATALIA LEVKOVICH	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/21/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-12* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/04/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendments filed on 01/08/2009 have been acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Election/Restrictions

3. Applicant's election of the apparatus claims 1-3 and 5-9 made in the reply filed on 04/21/2010 has been acknowledged. Accordingly, claims 10-12 have been withdrawn from further consideration as being directed to the non-elected invention. Since Applicant has not provided any specific arguments pertaining to the basis of the restriction requirement, the election is treated as being made without traverse.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the respective openings of the first and second gas exhaust

holes, as well as the individual channels having rectangular cross-sections and measurement sites, must be clearly shown and referenced, or the feature(s) canceled from the claim(s). No new matter should be entered. Additionally, in Figure 6, different reference characters '51A' and 53, as well as 51B and 54, appear to point to the same element, and the same reference character 51 appears to be assigned to different elements.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3 and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, recites a 'plurality of first gas exhaust holes each having an opening closed by a first seal and a second gas exhaust hole having an opening closed by a second seal; wherein each individual channel includes a reaction site and a branch offset from the reaction site toward the liquid inlet, the branch communicating with a corresponding one of the plurality of first exhaust holes and wherein the common channel communicates with the second gas exhaust hole'. The recitation of 'a corresponding one of the plurality of first exhaust holes', lacks antecedency, since the claim does not set forth any structural inter-relationships between the exhaust holes and the individual channels that include branches and reaction sites. In this connection, it is unclear how a hole can exist by itself, i.e., without being arranged in a solid body, 9for example, in a substrate). It is also unclear whether or not the apparatus intends a single first seal or multiple ones. Additionally, the 'hole having an opening', is unclear because the common meanings of the terms 'hole' and 'opening' are interchangeable.

With respect to claim 5, it is not clear whether or not the 'common circle' is the same as the 'common channel' recited in claim 1. The same consideration applies to the measurement sites of the individual channels recited in claim 5 and the reaction sites of the individual channels recited in claim 1.

Claim 7 recites reagent parts provided at 'selected ones of the reaction sites'. It is unclear whether any site selection means are intended.

In claim 8, 'the substrate' and 'the cover', lack antecedent basis.

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Claim Rejections - 35 USC § 102

7. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as anticipated by Tiffany et al. (US 3864089).

With respect to claims 1-3, 5-6 and 8, Tiffany discloses a disk shaped analyzing tool comprising, as shown in Figures 1 and 2, liquid inlet 6 provided at a central portion; a plurality of individual channels 7, 8 which communicate with the liquid inlet; common channel 9, 10 provided at the peripheral portion of the tool and communicating with the plurality of individual channels 7, 8 connected to chambers 4 ['reaction sites' and / or 'measurement sites']; rotor portion 3 ['substrate'] and cover disk 18 'cover']. Figure 1 also shows a diagonal portion of channel 7 ['branch offset from the reaction site toward the liquid inlet'] and vacuum annulus 12 ['second gas exhaust hole'] configured to be closed by annular sealing disk 13 ['second seal']. The outer end portions of channels 8 ['plurality of first gas exhaust holes each having an opening'] are capable of

being closed by the outer surface portions ['first seal9s)'] of the inner wall of the removable channel 9 when the removable channel is displaced relative to the rotor portion 3 and the outer surface portions of the wall abut the outer end portions of channels 8. It is also noted that, since the first and second seals are not positively recited as a part of the claimed invention, they are not accorded any patentable weight.

Regarding claim 7, Tiffany teaches that the reaction sites 4 can be provided with liquids ['reagent parts'], containing different washing and / or hemolyzing agents['reagents'] – (see Col.2, lines 40-41).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tiffany et al.

Tiffany does not specifically teach the width and the depth of the channels to be within the range of values as recited. However, the channels having the depth and width within the broad range of tens and hundreds of microns are routinely employed in fluidic circuits. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have modified the apparatus of Tiffany by optimizing the channel sizes in the same manner (depending on particular goals of testing), in order to diversify the tests to be performed.

Double Patenting

11. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 5 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 9-14 of co-pending US application 10/529120. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the elements of the invention recited in the instant claims, are entirely within the scope of claims 1 and 9-14 of the co-pending US application 10/529120. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 23 of co-pending US application 10/514010. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the invention recited in the instant claim 1, overlap in scope with the scope of claim 23 of the co-pending US application 10/514010.
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. Applicant's arguments filed on 01/08/2009 have been fully considered but they are moot in view of the new grounds of rejection.

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Natalia Levkovich/
Examiner, Art Unit 1797